



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/030,832	02/26/98	HANNA	M 1488.0950001

HM12/0327
STERNE, KESSLER, GOLDSTEIN & FOX
1100 NEW YORK AVENUE, N.W.
WASHINGTON DC 20005-3934

EXAMINER	
LANDSMAN, R	
ART UNIT	PAPER NUMBER

1646
DATE MAILED: 03/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/030,832

Applicant(s)

HANNA ET AL

Examiner

Robert Landsman

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 95-147 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 95-147 is/are rejected.
- 7) ☐ Claim(s) 97, 100, 103, 106, 108, 120, 129 and 141 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.

- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☒ Other: Sequence Comparisons A-D.

Art Unit: 1646

DETAILED ACTION

A. In the Office Action dated December 8, 1999, the Previous Examiner restricted the present inventions into three Groups since they are directed to different products, each appearing to constitute patently distinct inventions. Applicants elected Group II (claims 95-147) with traverse, stating that the search and examination of the Groups would not entail a serious burden.

The Examiner feels that there would be an undue burden of search since each of the Groups relates to a patentably distinct invention. The polynucleotide of Group II is distinct from that of Group I. A search of the polynucleotide of Group II would not necessarily provide information regarding the polynucleotide of Group I. Each invention would require its own database search. Similarly, the polypeptide of Group III is distinct from the polynucleotide of Group II and each would require its own search. Groups I and III are inextricably linked because the polypeptide of Group III could be synthesized by the polynucleotide of Group I, or could be chemically synthesized by the hand of man. For these reasons the restriction is deemed proper by the Examiner.

B. None of the NCBI Entrez Nucleotide Queries (AT16-AS20) were not considered since they could not be found. Please re-submit all of these queries for consideration.

1. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1646

C. Claims 95, 98, 101, 104, 115 and 117 are rendered indefinite because it is not understood what is meant by “allow gaps of up to 5% of the total number of residues.” This could be interpreted as (1) the total number of gaps can be 5% or less of the total number of amino acid residues, or (2) the total number of gaps can be 5% or less of the total number of polynucleotides, or (3) the length of *each* gap can be 5% or less of the total number of amino acid residues. Also, if the Bestfit program is a trademark, it should be noted as such in the claim with the appropriate registration mark.

In addition, the recitation of this program in the claims is also confusing. It is possible that the parameters and algorithms of these programs are constantly altered as various new programs are brought to market, making old programs obsolete. Therefore, if a newer version of the Bestfit program was used there may be some alterations in the way percent identity is calculated. For this reason, the claims should be amended to, for example (without adding new matter), recite the algorithm used in the calculation of percent identity. Claims 96, 97, 99, 100, 102, 103, 105-114, 116 and 118 to 126 are rejected since they depend from rejected base claims.

Claim 127 is rendered indefinite because of the terms “first” and “second.” These terms make the claim confusing. It is not clear whether the “first polynucleotide” or the “second polynucleotide” consist of the nucleotide sequence. The claim should be amended to remove the words “first” and “second.” Claims 128-135 are rejected since they depend from rejected base claim 127.

2. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1646

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

D. Claims 95-107, 109-113, 115-119, 121-125, 127-128, 130-134, 136-140, 142-146 are rejected under 35 U.S.C. 102(a) as being unpatentable by Davies et al. The claims are directed to an isolated polynucleotide identical to various defined regions of SEQ ID NO:41, which encode an amino acid sequence which is 95% identical to SEQ ID NO:42, or portions thereof. The claims are also directed to heterologous polynucleotides, a vector, a host cell and a method for producing a polypeptide. Davies et al. disclose an isolated polynucleotide which is 100% identical to SEQ ID NO:41 (Sequence Comparison A). They also disclose an amino acid sequence which is 100% identical to SEQ ID NO:42 (Sequence Comparison B; also page 820). Davies et al. also disclose a vector, a host cell and a method of making said polypeptide (page 823 under "Transient transfection of subunit cDNAs"). Since the polynucleotide was inserted into a vector, which comprises nucleotides encoding regulatory sequences and proteins, this isolated polynucleotide of Davies et al., therefore, contains a heterologous regulatory sequence. This polynucleotide would also hybridize to a full-length complement of SEQ ID NO:41. Claims 108, 120, 129 and 141 are objected to since they depend from rejected base claims.

E. Claims 95-96, 98-99, 101-102, 104-105, 107-147 are rejected under 35 U.S.C. 102(a) as being unpatentable by Garret et al. The claims are directed to an isolated polynucleotide which encodes an amino acid sequence which is 95% identical to SEQ ID NO:42, or portions thereof. Garret et al. disclose a polynucleotide (Sequence Comparison C) which encodes a polypeptide which is 99.5% identical to the polypeptide of SEQ ID NO:42 of the present invention (Sequence Comparison D). This polynucleotide also comprises at least 200 contiguous nucleotides of SEQ ID NO:41. Garret et al. also disclose a vector, a host cell and a method of making said polypeptide (page 1383 under "PCR Amplification"). Since the

Art Unit: 1646

polynucleotide was inserted into a vector, which comprises nucleotides encoding regulatory sequences and proteins, this isolated polynucleotide of Garret et al., therefore, contains a heterologous regulatory sequence, as well as heterologous polynucleotides. Claims 97, 100, 103 and 106 are objected to since they depend from rejected base claims.

3. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

F. Claims 108, 120, 129 and 141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al. in view of Reichmann et al. The claims are directed to an isolated polynucleotide which encodes a heterologous polypeptide. Davies et al. teach an isolated polynucleotide encoding an amino acid sequence which is 100% identical to amino acids 1-260 of SEQ ID NO:42. Davies et al. also teach the insertion of this DNA into a vector, producing a heterologous polynucleotide. Davies et al. do not teach the production of heterologous polypeptides. However, Reichmann et al. do teach the production of heterologous polypeptides by use of a vector containing heterologous polynucleotides (page 1113 under "Retroviral Infection").

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Davies et al., which teaches an isolated polynucleotide which is 100% identical to SEQ ID NO:41 (Sequence Comparison A) inserted into a vector as well as a host cell and a method of making said polypeptide (page 823 under "Transient transfection of subunit cDNAs") by

Art Unit: 1646

substituting the c-fos gene, which was inserted in-frame into the vector containing the hormone-binding domain of the human estrogen receptor, with the polynucleotide of Davies et al. to produce a fusion protein.

One of ordinary skill in the art would have been motivated to substitute the polynucleotide of Davies et al. for the c-fos polynucleotide of Reichmann et al. since the production of fusion proteins is a well-known method of purifying proteins. There would have been a reasonable expectation of success for a person of ordinary skill in the art to perform the invention of Davies et al. using the expression construct of Reichmann et al. since DNA digestion and ligation procedures are a widely used and highly successful means of linking DNA molecules.

G. Claims 114, 126, 135 and 147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al. The claims are directed to a method of recovering a polypeptide which is 95% identical to that encoded for by the isolated polynucleotide in ATCC Deposit No. 209642. Davies et al. disclose an isolated polynucleotide which is 100% identical to the polynucleotide of ATCC Deposit No. 209642, which is nucleotide numbers 11-1593 of SEQ ID NO:41 (Sequence Comparison A). Davies et al. also disclose a vector, a host cell and a method of making said polypeptide (page 823 under "Transient transfection of subunit cDNAs"). Davies et al. do not teach recovering the polypeptide.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have recovered the polypeptide in order to do enzymatic digestion assays of the protein, to produce antibodies and to determine the structure of the protein. There would have been a reasonable expectation of success for a person of ordinary skill in the art to recover the polypeptide since the methods of recovering polypeptide from cells are well-known, widely used and highly successful in the art.

Art Unit: 1646

Advisory information

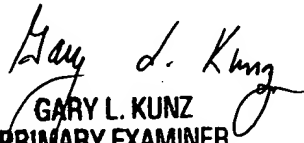
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
March 24, 2000


GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200